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From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY  
(PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/GB2004/002845

International filing date (day/month/year)  
01.07.2004

Priority date (day/month/year)  
01.07.2003

International Patent Classification (IPC) or both national classification and IPC  
A61K7/40, A61K7/42

Applicant  
HYGIEIA PHARMACEUTICALS LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office - P.B. 5818 Patentlaan 2  
NL-2280 HV Rijswijk - Pays Bas  
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl  
Fax: +31 70 340 - 3016

Authorized Officer

Menidjel, R

Telephone No. +31 70 340-3680



10/560457

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INTERNATIONAL SEARCHING AUTHORITYInternational application No.  
PCT/GB2004/002845

IAP20 R3C 1757710 13 DEC 2005

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ in written format
    - ☐ in computer readable form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in computer readable form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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**Box No. II    Priority**

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1. ☒ The following document has not been furnished:☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

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PCT/GB2004/002845**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,  
☒ claims Nos. 18-20

because:

- ☒ the said international application, or the said claims Nos. 18-20 relate to the following subject matter which does not require an international preliminary examination (*specify*):

**see separate sheet**

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
- |                            |  |
|----------------------------|--|
| the written form           | <input type="checkbox"/> has not been furnished            |
|                            | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished            |
|                            | <input type="checkbox"/> does not comply with the standard |
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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## 1. Statement

Novelty (N)	Yes: Claims	8,9,16,17
	No: Claims	1-7,10-15,18-22
Inventive step (IS)	Yes: Claims	
	No: Claims	1-22
Industrial applicability (IA)	Yes: Claims	1-17,21,22
	No: Claims	

## 2. Citations and explanations

**see separate sheet**

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING  
AUTHORITY (SEPARATE SHEET)

International application No.

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IAP20 Received 13 DEC 2005

Re Item III**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

- The subject-matter of claims 18-20 is related to a method for treatment of the human or animal body from surgery or therapy. Using its discretion, the present authority decided not to carry out an international preliminary examination on that subject-matter (Article 34(4)(a)(I) PCT in conjunction with Rule 67.1(iv) PCT).

Re Item V**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1 - The following documents (D1,D2,D3) are referred to in this communication (Article 33(6) PCT); the numbering will be adhered to in the rest of the procedure:

D1: US-A-5 648 083 (DECKNER GEORGE ENDELL ET AL) 15 July 1997 (1997-07-15)

D2: US-B-6 387 3821 (SALEH MICHAEL ET AL) 14 May 2002 (2002-05-14)

D3: US-A-5 208 013 (KLEIN KENNETH) 4 May 1993 (1993-05-04)

**2. Clarity (Article 6 PCT)**

a - Claim 1 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. Present claim 1 refers to a formulation wherein the viscosity of said formulation is 20000 cps or less.

It should be borne in mind that, it may happen that in the relevant prior art, a different parameter or no parameter at all is mentioned. If the known and the claimed product are identical in all other respects, then in the first place an objection of lack of novelty arises.

b - The unit, e.g. centipoise expressed, e.g. in claim 1 and in the description does not meet the requirements of Rule 10.1(a) and (b) PCT and should be replaced by the appropriate SI units. The present expressions should, however, be retained in parentheses after the replacement expressions.

✓ Pa-s - Cl. 1  
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c - The word "approximate ranges" found in claim 9 and in the description should not be used in connection with ranges of values as it leaves the reader in doubt as to the definition of the matter for which is sought, contrary to Article 6 PCT. The use of this term prevents the invention from being distinguished from the prior art with respect to novelty (Article 33(2) PCT) and/or inventive step (Article 33(1),(3) PCT). → delete word

In this regard, it is noted that an unclear term cannot be used to distinguish the claimed

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+ Pg 11, 17

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subject-matter over the state of the art, since this leads to both a lack of clarity pursuant Article 6 PCT and to a lack of novelty of the claim in accordance with Article 33(2) PCT.

d - Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art is not mentioned in the description.

**3. Novelty (Article 33(2) PCT)**

- The subject-matter of present claims 1-7,10-15,18-22 is considered as not novel over the cited prior art (Article 33(2) PCT):

- Document D1 describes a personal care formulation which comprises an emulsion having an oil phase comprising a silicone compound and an aqueous phase, the formulation further comprising an active ingredient, and one or more emollient, excipient, a thickener, an emulsifier, a preservative agent and a neutralising agent (Cf. D1, column 3, line 30-line 51; column 4, line 11-column 5, line 28; column 7, line 23-column 8, line 14; column 8, line 36-line 66; column 11, line 18-line 33).

The subject-matter described in document D1 takes away novelty of present claims 1-5,7,10-15,18-22.

- Document D3 refers to a composition for skin care and protection which comprises an oil phase comprising a silicone compound and an aqueous phase, the formulation further comprising an active ingredient, and one or more emollient, excipient, a thickener, an emulsifier and a preservative agent (Cf. D3, column 1, line 60-line 65; column 2, line 39-column 3, line 2; column 4, line 3-line 19; claims 1-5).

The subject-matter described in document D2 takes away novelty of present claims 1-7,10-15,18-22.

**4. Inventive Step (Article 33(1),(3) PCT)**

a - Since the subject-matter of present claims 1-7,10-15,18-22 is known, it can obviously not be considered as inventive (Article 33(1),(3) PCT).

b - The remaining subject-matter, which is the subject-matter of present claims 8,9,16,17 does not involve an inventive step for the following reasons (Article 33(1),(3) PCT):

- The subjective problem to be solved by the present application is to provide a barrier formulation which keeps its properties during a long time after application and which does not have to be frequently re-applied.

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- The solution proposed in the present application is a barrier formulation as described in present claim 1.
- Document D3, which is considered as the closest prior art, describes a composition for skin care and protection which comprises an oil phase comprising a silicone compound and an aqueous phase, the formulation further comprising an active ingredient, and one or more emollient, excipient, a thickener, an emulsifier and a preservative agent (Cf. D3, column 1, line 60-line 65; column 2, line 39-column 3, line 2; column 4, line 3-line 19; claims 1-5).
- The difference between the teaching of the closest prior art and the claimed subject-matter is the presence of a fragrance in said formulation and the use of said formulation in the manufacture of a medicament for the treatment and/or prophylaxis of mastitis infection and the treatment and/or prophylaxis of teat sores in animals.
- The feature of claims 8,9,16,17 is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.  
Therefore, the subject-matter of present claims 8,9,16,17 does not involve an inventive step (Article 33(1),(3) PCT).

The applicant is requested to file new claims which take account of the above comments.

The applicant is requested to file amendments by way of replacement pages in the manner stipulated by Rule 66.8(a) PCT. In particular, fair copies of the amendments should be filed preferably in triplicate. He is invited to file new claims and adapt description, in particular by deleting passages referring to aspects of the inventions which do not correspond to claimed subject-matter (Article 6 PCT).

The amendments filed by the applicant should not introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT.